

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., ET AL.,)	
)	
Plaintiffs,)	C.A. No. 08-21-GMS-LPS
)	(Consolidated)
)	
v.)	PUBLIC VERSION
)	
COBALT LABORATORIES INC., ET AL.,)	
)	
Defendants.)	

**REPLY BRIEF OF DEFENDANT ORCHID CHEMICALS & PHARMACEUTICALS
IN FURTHER SUPPORT OF ITS MOTION TO DISMISS
FOR LACK OF PERSONAL JURISDICTION**

AND

OPPOSITION TO PLAINTIFFS' CONTINGENT MOTION TO TRANSFER

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I. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs brought this action for patent infringement under 35 U.S.C. § 271(e)(2) against Orchid Chemicals & Pharmaceuticals Ltd. (“Orchid India”) and Orchid Pharmaceuticals Inc. (“Orchid Delaware”) premised on Orchid’s filing of Abbreviated New Drug Application (“ANDA”) No. 90-044 with the Food and Drug Administration (“FDA”) for a generic memantine hydrochloride product. Orchid’s ANDA included a paragraph IV certification that the sale of its proposed memantine product would not infringe any valid patent claim of U.S. Patent No. 5,061,703 (“the ’703 patent”). *See* Complaint at ¶¶ 45-49. Plaintiffs Forest Laboratories, Inc. (“Forest Labs”) and Forest Laboratories Holdings, Ltd. (collectively, “Forest”) and Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, as “Merz”), claim that they own all substantive rights in the ’703 patent, which they maintain covers “Namenda® brand” memantine hydrochloride tablets. Complaint at ¶¶ 27-28.

In response to the Complaint, Orchid India filed a Rule 12(b)(2) Motion To Dismiss For Lack Of Personal Jurisdiction. Plaintiffs opposed Orchid India’s motion and also filed a Contingent Cross-Motion for Transfer. Orchid India hereby submits this brief in reply to Plaintiffs’ opposition and opposition to Plaintiffs’ Contingent Cross-Motion for Transfer.

II. SUMMARY OF ARGUMENT

Plaintiffs brought this case against Orchid India¹ under the Hatch-Waxman Act, which makes the filing of an ANDA containing a paragraph IV certification a “highly artificial” act of infringement. Orchid India is not accused of committing any of the traditional acts of patent infringement, such as the manufacture, use, offer for sale, or sale of infringing product. In fact,

¹ Plaintiffs have also sued Orchid Delaware, which is a wholly-owned subsidiary of Orchid India and incorporated in Delaware. Orchid Delaware is a holding company and had nothing to do with the preparation or filing of ANDA No. 90-044. Orchid Delaware intends to promptly seek leave to move for summary judgment that it did not infringe the ’703 patent.

Plaintiffs' Complaint seeks an injunction prohibiting any such action by Orchid India prior to the expiration of the '703 patent. Rather, Orchid India is accused of "patent infringement" for filing an ANDA requesting permission to market memantine hydrochloride – a "legal fiction" that does not take advantage of any state's commercial laws and legal structures nor does it target any state's residence. *See, e.g., Zeneca Ltd. v. Mylan Pharmas, Inc.*, 173 F.3d 829, 836 (Fed. Cir. 1999) (Rader, J. concurring).

As set forth in detail in its Opening Brief, Orchid India is not subject to specific jurisdiction in Delaware, either under the Delaware long-arm statute or the Due Process Clause. Orchid India has only tenuous and attenuated contacts with Delaware—it has no established "continuous and systematic general business contacts" with Delaware. Orchid India has not availed itself of Delaware resources in that Orchid India has no employees, bank accounts, or real estate in Delaware. Orchid India does not solicit business, through advertising or otherwise, in Delaware. Orchid India derives no revenue from Delaware. Orchid India has no license to sell pharmaceutical products in Delaware, and is not registered with the Secretary of State to do business in Delaware. No agent of Orchid India has taken any action in Delaware relating to ANDA No. 90-044—let alone any such action that can be attributed to Orchid India. Finally, although Orchid India wholly owns a subsidiary in Delaware, that subsidiary indisputably played no role in preparing or filing ANDA No. 90-044. Moreover, because the subsidiary is not the alter-ego or general agent of Orchid India, Orchid India's mere ownership is insufficient to establish substantial activities in Delaware in any event.

Because Orchid India does not fit with any personal jurisdiction theory, Plaintiffs offer a wide range of varying theories, accusations, and irrelevant facts in its effort to establish jurisdiction over Orchid India. However, Plaintiffs cannot cite a single case where any court has

found specific jurisdiction over a defendant for filing an ANDA or found general jurisdiction where the defendant's contacts with the forum state were as attenuated as those of Orchid India with Delaware. Instead, there are numerous cases where this Court held that personal jurisdiction did not exist over defendants with substantially greater and more sustained contacts with Delaware than does Orchid India. In these circumstances, Orchid India should be dismissed for lack of personal jurisdiction.

Further, Plaintiffs' alternative motion to transfer instead of dismissal is properly denied. Where, as here, Plaintiffs have failed to carry their burden of establishing that this entire case could have been brought in the District of New Jersey, or that the interests of justice require such a transfer, the appropriate remedy is dismissal without prejudice, not transfer.

III. ARGUMENT

Orchid India does not have contacts with the State of Delaware sufficient to merit the exercise of either specific or general personal jurisdiction over it by this Court. Specific jurisdiction does not exist because the only alleged act of infringement—the filing of ANDA No. 90-044—did not take place here. The same is true of the development and formulation work. General jurisdiction is lacking because Orchid India does not have the requisite systemic contacts with Delaware to merit the exercise of jurisdiction over Orchid India for a claim entirely unrelated to its limited contacts with the State.

A. There Is No Personal Jurisdiction Over Orchid India Under Delaware's Long-Arm Statute

1. This Court Does Not Have Dual Jurisdiction Over Orchid India

a. The Relevant Legal Standards

The concept of dual jurisdiction is a theory of specific jurisdiction. *See Power Integrations, Inc. v. BCD Semiconductor Corp.*, 547 F. Supp. 2d 365, 371 (D. Del. 2008); *Merck*

& Co., Inc. v. Barr Labs., Inc., 179 F. Supp. 2d 368, 374 (D. Del. 2002) (“[T]he Delaware Superior Court stated in *Boone v. Oy Partek AB* that the stream of commerce theory ‘rests on a specific rather than a general jurisdiction rationale.’”). The Delaware Superior Court in *Boone* held that dual jurisdiction may be appropriate only “when a manufacturer has sufficient general contacts with Delaware *and plaintiffs’ claims arise out of those contacts.*” *Boone v. Oy Partek AB*, 724 A.2d 1150, 1157 (Del. Super. 1997) (emphasis added). Thus, dual jurisdiction may potentially exist only “if the intent or purpose on behalf of the manufacturer to serve the Delaware market *results in the introduction of the [accused] product to this State and* plaintiff’s cause of action arises from injuries caused by that product.” *Boone*, 724 A.2d at 1158.

As set forth below, dual jurisdiction is inapplicable because (1) Orchid India’s proposed generic memantine product has not been introduced “into this State,” and (2) Plaintiffs’ purported cause of action does not (and cannot) arise out of the presence of that product in Delaware.

b. Orchid India Has No Contacts With Delaware Related To ANDA No. 90-044 And No Accused ANDA Product Was Ever Present Or Sold In Delaware

Dual jurisdiction requires proof of the “introduction of the [accused] product to this State.” *See Boone*, 724 A.2d at 1158; Pl. Mem. in Opp. at 8 (acknowledging that dual jurisdiction theory has only been applied where a defendant’s distribution network “caused the allegedly infringing products to be sold and distributed in Delaware.”). It is undisputed that Orchid’s proposed generic memantine product has never been introduced into Delaware. Indeed, as Plaintiffs note, “[a] generic drug company may not market a given drug in the United States unless that drug is the subject of an FDA-approved ANDA.” Pl. Mem. in Opp. at 10 n.9. Because Orchid India does not yet have such approval—indeed, Plaintiffs’ lawsuit seeks to

preclude Orchid India from obtaining such approval—its accused product has not been “sold and distributed in Delaware,” and the dual jurisdiction theory axiomatically does not apply.

Plaintiffs’ request that this Court predicate a finding of personal jurisdiction on the supposition that Orchid may in the future distribute its proposed generic memantine product in Delaware is unsupported by any case law. Plaintiffs cite no case (and Orchid is aware of none) in which the dual jurisdiction theory was applied even though the accused product had not been distributed into Delaware and allegedly caused injury there. Indeed, Plaintiffs’ request is foreclosed both by the Delaware cases cited above and the fact that “personal jurisdiction contacts are determined at the time the initial complaint is filed.” *Allen v. Russian Fed.*, 522 F. Supp. 2d 167, 194 (D.D.C. 2007). *See also Dole Food Co. v. Patrickson*, 538 U.S. 468, 478 (2003) (noting the “longstanding principle that ‘the jurisdiction of the Court depends upon the state of things at the time of the action brought.’”). Thus, Plaintiffs’ supposition that Orchid’s proposed memantine ANDA product may be distributed in Delaware in the future—once Orchid receives final approval from the FDA—is irrelevant to the question of whether Orchid was amenable to personal jurisdiction in Delaware as of the date that the Complaint was filed.

In any event, Plaintiffs’ unsupported speculation that the “same channels that Orchid India currently uses to distribute its products would also be used to distribute” Orchid India’s proposed memantine product if approved by FDA (Pl. Mem. in Opp. at 11-12) is simply wrong. In fact, Orchid India’s Rule 30(b)(6) designee Dr. Rao testified to the contrary:

Q. Do you know where the product that is the subject of ANDA 90-044 will be sold?

A. **We do not have any present distribution agreement for this product.**

Q. It's not exactly the question I asked. Do you know where it would be sold?

A. I believe if you have a distribution arrangement it will be sold in the United States of America, because this has been filed as an ANDA, and an ANDA has something to do with selling in United States. So I believe the intent is to make the product available in the United States. **But as of now, we do not have a distributor. Therefore, I am not sure whether it, in fact, will be sold in the United States.** But the intent is to develop a product which can be sold in the United States.

Ex. 5 (Transcript of June 13, 2008 Deposition of Dr. C. Bhaktavatsala Rao ("Rao Dep. Tr.") 49:5-50:3.

Plaintiffs' dual jurisdiction theory suffers from a separate and independent defect—the fact that their proposed cause of action has nothing whatsoever to do with the potential future sale of Orchid India's generic memantine product in the stream of commerce. Dual jurisdiction requires both that the accused product have been distributed in Delaware *and* that "plaintiff's cause of action arises from injuries caused by" the introduction of the accused product into Delaware. *Boone*, 724 A.2d at 1158. Plaintiffs' alleged cause of action against Orchid India arises *solely* out of the filing of ANDA No. 90-044. *See* Complaint at ¶¶ 45-49. It is undisputed that the ANDA was filed in Maryland by Orgenus, a New Jersey company, acting as the U.S. FDA regulatory agent for Orchid India.²

² Plaintiffs reference to the fact that "Orchid [Delaware], a wholly-owned subsidiary [of Orchid India], [] was incorporated in Delaware on October 6, 2004" (Pl. Mem. in Opp. at 9) proves nothing. Orchid Delaware has nothing to do with Plaintiffs' claim of infringement. Orchid Delaware did not participate in, contribute to, or otherwise aid in the preparation of ANDA No. 90-044 or in its submission to FDA. *See* Ex. 3 (Rao Decl.) at ¶ 16; Ex. 4 (Srinivasan Decl.) at ¶ 8. Plaintiffs have provided no evidence to the contrary. And while Plaintiffs cite to a 2004 Annual Report in suggesting that Orchid Pharma has in the past acted as Orchid's regulatory agent (Mem. in Opp. at 9 & n.8), the undisputed facts show that the accused ANDA No. 90-044 was filed by Orgenus Pharma as regulatory agent for Orchid. *See* Ex. 6 (submission documents for ANDA No. 90-044 indicating that Orgenus is the U.S. Agent); Pl. Mem. in Opp. at 6 ("Orgenus served as Orchid India's U.S. regulatory agent for the filing of this ANDA.").

Plaintiffs' argument that Orchid allegedly obtained components for its proposed generic memantine product "from companies located *in the United States*" (Pl. Mem. in Opp. at 10) is both irrelevant (as it has nothing to do with Delaware) and fatally flawed in any event.³ As discussed below, Plaintiffs grossly overstate the connections between Delaware and the preparation process for the ANDA. Even if such assertions were true, Plaintiffs cite no case where the mere fact that a foreign entity may have utilized materials that may have been manufactured in a state as part of the process of preparing an ANDA is sufficient to support jurisdiction, and we are aware of none. Further, the provenance of any such alleged components is immaterial since it is clear that the only material alleged to have been manufactured in Delaware (Pl. Mem. in Opp. at 17-18) was purchased from an Indian supplier in India.⁴

2. This Court Does Not Have General Jurisdiction Over Orchid India

Plaintiffs argue perfunctorily that Orchid India's contacts with Delaware were so continuous and substantial that general jurisdiction exists over it. However, Plaintiffs meager catalogue of all of the contacts that Orchid India has with Delaware, if anything, establishes that Orchid India's contacts with Delaware are so rare and nonsubstantive that there can be no general jurisdiction over Orchid India in Delaware.

To establish general jurisdiction, Plaintiffs "must show significantly more than mere minimum contacts," and must establish that Orchid India's contacts with Delaware were

³ Plaintiffs cite the deposition of Dr. Rao, who said no such thing. Dr. Rao consistently testified that materials are obtained from Indian suppliers. For example, Dr. Rao testified that: "We normally place orders to the agents who are available in India." Ex. 5 (Rao Dep. Tr.) 40:25-41:2. *See also id.* at 41:15-16 ("I'm saying that we buy from local agents in India."); *id.* at 42:17-20 ("These are some of the ready materials which are used as spot purchase activities through, as I said, Indian agents who supply these products.").

⁴ Dr. Rao testified that the Microcrystalline Cellulose ("MCC") used for its memantine ANDA exhibit batches was purchased from Signet Chemical Corporation in India. Ex. 5 (Rao Dep. Tr.) 155:4-11.

“continuous and substantial.” *Foster Wheeler Energy Corp. v. Metallgesellschaft AG*, C.A. No. 91-214-SLR, 1993 WL 669447 at * 3 (D. Del. Jan. 04, 1993) (quoting *Provident Nat’l Bank v. California Fed. Sav. & Loan Ass’n*, 819 F.2d 434, 437 (3d Cir. 1987)); *Gehling v. St. George’s Sch. of Med., Ltd.*, 773 F.2d 539, 541 (3d Cir. 1985)). Such contacts merit the exercise of general jurisdiction over a corporation only when “the continuous corporate operation within a state [is] thought so substantial and of such a nature as to justify suit against it on causes of action arising from dealings entirely distinct from those activities.” *International Shoe Co. v. Washington*, 326 U.S. 310, 318 (1945).

Plaintiffs do not dispute that Orchid India has no employees, local telephone listing, bank account, or real estate in Delaware; does not solicit business (by way of advertising or promotion) in Delaware; does not derive substantial revenue from services or things used or consumed in Delaware; and has never sold any of its products to a customer located in Delaware. *See* Mem. in Supp. at 4-5, 8, 11; Pl. Mem. in Opp. at 13-15.

The fact that Orchid India has a subsidiary incorporated in Delaware (Pl. Mem. in Opp. at 14), does not confer general jurisdiction over Orchid India. Plaintiffs maintain that Orchid Pharma has done little more than that necessary to maintain status as a Delaware corporation. *See* Pl. Mem. in Opp. at 23. But where a company has “done little more in Delaware than is necessary to comply with corporate formalities, this activity is insufficient to meet the terms of subsection (c)(4).” *Applied Biosystems Inc. v. Cruachem, Ltd.*, 772 F. Supp. 1458, 1467 (D. Del. 1991). *See also* *Sears, Roebuck & Co. v. Sears plc*, 744 F. Supp. 1297, 1306 (D. Del. 1990) (“Sears II”). Thus, the existence of Orchid Delaware does not merit the exercise of general jurisdiction over its parent.

The fact that there two Orchid India contracts with a Delaware choice of law provision is similarly unavailing. *See* Pl. Mem. in Opp. at 15. Delaware courts have refused to base personal jurisdiction solely on the existence of such a choice of law provision, *see Intellimark, Inc. v. Rowe*, C.A. No. 05-C-01-086-PLA, 2005 WL 2739500 at * 2 (Del. Super. Ct. Oct. 24, 2005), even when the Delaware choice of law provision was in a contract related to plaintiff's cause of action. *See Summit Investors II, L.P. v. Sechrist Indus., Inc.*, C.A. No. 19400, 2002 WL 31260989 at * 4 (Del. Ch. Sept. 20, 2002).

The fact that four representatives of Orchid India made a single visit to DuPont in Delaware likewise fails to prove sustained contact with the State. The visit did not even involve the conduct of any business related to Plaintiffs' cause of action. The visit involved a safety program in which both Orchid India and DuPont India (not DuPont, Delaware) participate. *See* Ex. 5 (Rao Dep. Tr.) 19:7-20:13. The representatives merely visited a typical DuPont work site and visited a DuPont museum. *Id.*

Finally, the existence of a handful of supply agreements with companies located outside Delaware—but allegedly incorporated in Delaware—falls far short of creating general jurisdiction. Initially, Orchid India sells products to various distributors, who distribute the products as they see fit without any direction from Orchid India. *See* Ex. 5 (Rao Dep. Tr.) 50:21-51:19. None of the revenue Orchid India receives from its sales to corporations pursuant to those supply agreements can be considered as revenue Orchid India derives from Delaware because the nexus—the mere fact that one party to the contract is incorporated in Delaware—is too attenuated. *See Merck*, 179 F. Supp. at 372-73 (holding that the sale and distribution of \$1.2 million per month of a drug in Delaware through a company incorporated in Delaware was not attributable to defendant).

Plaintiffs have cited no case, and we are aware of none, supporting the exercise of general jurisdiction where the contacts with Delaware are as attenuated as they are here. Rather, the case law is uniformly to the contrary. *See, e.g., Merck*, 179 F. Supp. at 372, 375 (holding in ANDA case that two licenses to sell products in Delaware, direct sales to Delaware pharmacy, contract for sale and distribution of \$1.2 million of drug per month in Delaware, and substantial revenue from Delaware from drugs in the stream of commerce only amount to insignificant contacts); *Applied Biosystems*, 772 F. Supp. at 1462, 1470 (characterizing the reincorporation of a Delaware subsidiary, attending meeting in Delaware to discuss joint venture, sending free sample of accused product into Delaware, national advertising, and receiving substantial financing from Delaware as “forum contacts [] too few, too insubstantial, and too unrelated to the causes of action to enable us to exercise jurisdiction over” the foreign defendants); *Monsanto*, 443 F. Supp. 2d at 643-46 (holding that ownership of a Delaware subsidiary, attending a meeting in Delaware, final say over whether subsidiaries would market the accused product, and an overlap of some officers and directors insufficient contacts). In each of these patent infringement cases the defendant had substantially more contacts with Delaware than does Orchid India. And, in each of these cases the Court rejected claims that such contacts supported the exercise of general jurisdiction.

3. This Court Does Not Have Specific Jurisdiction Over Orchid India Under Subsection (c)(3)

a. The Relevant Legal Standards

Relying on Section (c)(3) of the Delaware long arm statute, Plaintiffs maintain that Orchid India is subject to personal jurisdiction because it allegedly caused “tortious injury in the State by an act or omission in this State.” 10 Del. Code § 3104(c)(3). *See* Pl. Mem. in Opp. at 19-20. Subsection (c)(3) provides for specific jurisdiction, such that the subject cause of action

must arise from the defendant's contacts with the forum. *See Sears, Roebuck & Co. v. Sears plc*, 744 F. Supp. 1289, 1292 (D. Del. 1990) ("*Sears I*"); *LaNuova D & B, S.p.A. v. Bowe Co., Inc.*, 513 A.2d 764, 768 (Del. 1986). Because subsection (c)(3) requires "an act or omission in this State," the Plaintiffs bear the burden of (1) identifying an act or omission by Orchid India that occurred "in this State," and (2) articulating how their claim for patent infringement under 35 U.S.C. § 271(e)(2) arose from that act or omission. *See LaNuova*, 513 A.2d at 768. Plaintiffs have failed to satisfy either predicate.

b. Orchid Committed No "Act or Omission in this State"

Plaintiffs argue that jurisdiction exists under Subsection (c)(3) because "Orchid India sent notice of its Paragraph IV certification to Forest Labs, a Delaware corporation, on or about December 7, 2007, and alleged that the '703 patent was invalid and not infringed by Orchid India's proposed memantine hydrochloride product." Pl. Mem. in Opp. at 19. Plaintiffs' argument misapprehends the requirements of Subsection (c)(3). "Simply put, in order for a defendant to commit an act in Delaware and be subject to subsection (c)(3), *the defendant*, or an agent of the defendant, *must be present in Delaware when the deed is done.*" *Sears I*, 744 F. Supp. at 1294. Indeed, courts have specifically held that the only "act" specified by Plaintiffs—mailing a notice letter—is not one that is deemed to have taken place within the State even where the mailing is sent to a Delaware address:

The "act" of mailing, for purposes of subsection (c)(3), is complete when the material is mailed. Any other interpretation of the statute would mean that anytime tortious injury was felt in Delaware, the alleged tortfeasor could be deemed to have committed an "act" in Delaware. . . . [and] would "eviscerate the distinction between subsections (c)(3) and (c)(4)"

Sears I, 744 F. Supp. at 1294. Orchid India sent its notice letter to Forest Labs at their headquarters in New York, New York. Given that Orchid India's notice letter was not even

mailed to an addressee in Delaware, Plaintiffs' invocation of Subsection (c)(3) is squarely foreclosed under established law.

Even putting aside that fundamental defect, Plaintiffs' reliance on Subsection (c)(3) is misplaced because their purported cause of action did not arise out of the mailing of the "Paragraph IV certification to Forest Labs." Pl. Mem. in Opp. at 19. Rather, Plaintiffs' Complaint asserts that Orchid is allegedly liable for infringement because "Orchid's *submission of ANDA No. 90-044 to the FDA* . . . constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A)." Complaint at ¶ 47. Indeed, that is the only act that the Plaintiffs *could* allege as constituting infringement, as it is the one specified by Congress. *See* 35 U.S.C. § 271(e)(2)(A) (providing that "[i]t shall be an act of infringement to submit [] an application under section 505(j) . . . for a drug claimed in a patent or the use of which is claimed in a patent"). As the Supreme Court has noted, § 271(e)(2) creates "a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990). In short, the mailing of Orchid's notice letter was not an act of infringement—let alone the act of infringement of which Plaintiffs complain. For these independent reasons, Plaintiffs' invocation of Subsection (c)(3) of the Delaware Long Arm Statute fails.⁵

⁵ Plaintiffs' contention that "the most realistic situs of injury to Plaintiffs" is allegedly Delaware does not withstand scrutiny. *See* Pl. Mem. in Opp. at 19. First, even assuming that a licensee could be deemed to suffer injury, Delaware cases place the situs at the principal place of business, not the state of incorporation. *See, e.g., Foster Wheeler*, 1993 WL 669447 at n.7 (D. Del. 1993) ("Here, where [plaintiff's] sole Delaware contact is as [plaintiff's] state of incorporation, and [plaintiff's] principal place of business is in New Jersey, any injury for alleged infringement of [plaintiff's] patents occurred in New Jersey, not in Delaware."); *Applied*

Plaintiffs' remaining argument asks that this Court disregard the plain language of Subsection (c)(3) and decades of case law and re-write the Delaware Long Arm Statute to "require[e] Defendants to litigate in Forest Labs' home forum" because doing so would be more convenient for Forest. *See* Pl. Mem. in Opp. at 20-21. Plaintiffs' plea is better directed to the Delaware Legislature or the United States Congress—as this Court's job is to apply the law as written and not to ignore the plain meaning of State statutes in order to purportedly "bring much-needed predictability and certainty to ANDA litigations." Pl. Mem. in Opp. at 21. The Delaware Legislature has mandated that jurisdiction may only be exercised under Subsection (c)(3) of the Long Arm Statute where a defendant causes "tortious injury in the State by an act or omission in this State." 10 Del. Code § 3104(c)(3). The fact that Plaintiffs can identify no such act merely highlights the impropriety of Plaintiffs' effort to litigate against Orchid India in Delaware, as the State plainly has no cognizable connection to the controversy.

c. Jurisdiction Does Not Exist Under Subsection (c)(1)

(1) Standard of Review

Plaintiffs also rely upon Subsection (c)(1) of the Delaware Long Arm Statute—the "transacts business" provision. *See* Pl. Mem. in Opp. at 17-18. Like Subsection (c)(3), "subsection (c)(1) requires some act of the defendant *within the state*." *Sears I*, 744 F. Supp. at 1294. Moreover, Subsection (c)(1) relates to specific jurisdiction, such that the subject cause of action must arise from the defendant's contacts with the forum. *See LaNuova*, 513 A.2d at 768. To successfully invoke Subsection (c)(1), a plaintiff must show that the putative defendant (1)

Biosystems, 772 F. Supp. at 1468; *Power Integrations*, 547 F. Supp. 2d at 373; *Commissariat A L'Energie Atomique v. Chi Mei Optoelectronics, Corp.*, 395 F.3d 1315, 1318 (Fed. Cir. 2005). And in any event, the "mere filing of an ANDA does not at that point even cause a tangible injury to the patent holder." *Zeneca*, 173 F.3d at 836 (Rader, J., concurring). At most, any alleged "injury" would have been suffered in Germany, where the actual patent holder (Merz) resides. *See* Complaint at ¶¶ 3, 4, 27; Ex. 1 (License and Cooperation Agreement, dated June 28, 2000); Ex. 2 (Memantine Distribution Agreement, dated April 1, 2003).

transacted business in Delaware, (2) by taking an action within the State, and (3) out of which the cause of action arose. *See id.*

(2) Plaintiffs Wrongly Rely Upon Subsection (c)(1)

Plaintiffs contend that Orchid India is subject to jurisdiction under Subsection (c)(1) because “Orchid India’s proposed memantine hydrochloride tablets result from activities that have an unassailable connection to Delaware.” Pl. Mem. in Opp. at 17. But Plaintiffs’ theory merely sidesteps the requirements for asserting jurisdiction under Subsection (c)(1).

Initially, Subsection (c)(1) requires that Orchid India have taken an action “within the State,” *Sears I*, 744 F. Supp. at 1294, but the Plaintiffs fail to identify any such act. *See* Pl. Mem. in Opp. at 17-18. Indeed, even taking their assertions at face value, Plaintiffs have merely alleged that one of the excipients of Orchid’s proposed product “was manufactured by . . . a company located in Newark, Delaware,” that Orchid may use products manufactured by companies incorporated in Delaware “as packaging,” and that Orchid utilized another company incorporated in Delaware “to conduct clinical testing required by the FDA.” Pl. Mem. in Opp. at 17-18. But assuming for the moment that the Plaintiffs are correct, none of those circumstances would satisfy the requirement of “some act *of the defendant* within the state.” *Sears I*, 744 F. Supp. at 1294 (emphasis added).

Indeed, Plaintiffs’ assertions at best show highly attenuated connections with Delaware involving transactions that occurred wholly outside of the State (and, indeed, outside of the United States). Thus, for instance, the facts of record show that Orchid India’s purchase of the excipient MCC took place in India:

Q. Excipient S Number 1 is “Microcrystalline Cellulose,” is that correct?

A. Uh-huh.

Q. Under "Manufacturer/Supplier" it lists FMC BioPolymer in Newark, Delaware, is that correct?

A. Yes. But some of these things could also be supplied through several agents they have. It is not necessary that we order from them. We normally place orders to the agents who are available in India.

Q. Do you have any reason to believe that the manufacturer/supplier for Microcrystalline Cellulose is incorrect on this document?

A. I'm not saying it is incorrect. I'm saying that we buy from local agents in India.

Ex. 5 (Rao Dep. Tr.) 40:14-41:16 & Ex. 7 (Rao Dep. Ex. 7). The invoice for that purchase confirmed that the MCC was purchased from Signet Chemical Corporation in India and not from a supplier in Delaware. *See* Ex. 5 (Rao Dep. Tr.) 155:4-11 & Ex. 8 (Rao Dep. Ex. 20).

Plaintiffs' allegation that Orchid "will also use products manufactured by Delaware companies as packaging" also is mistaken. *See* Pl. Mem. in Opp. at 18. In fact, none of the companies listed by Plaintiffs as examples of "Delaware companies" are located in Delaware. Chevron Philips Chemical Company is located in The Woodlands, Texas; Rexam Closures and Containers is located in Evansville, Indiana; and Selig Sealing Products, Inc is located in Forrest, Illinois. *See* Ex. 7 at OCP5002. Thus, even assuming that Orchid India directly transacted with those entities (rather than third-party suppliers of their products), none of those transactions would qualify as an "act of [Orchid India] within the state" of Delaware.

Plaintiffs' assertion regarding "clinical testing" is similarly misguided. *See* Pl. Mem. in Opp. at 18. AAIPharma, Inc.-AAI Clinic of Morrisville, North Carolina performed two bioequivalence studies for Orchid India at its center in Morrisville, North Carolina. *See* Ex. 9 at OCP2917-18 and Ex. 10 at OCP3834-35. In addition, AAIPharma performed pharmacokinetic

and statistical analyses for the clinical studies in Wilmington, North Carolina and bioanalytical work was performed in Shawnee, Kansas. *See* Ex. 9 at OCP2934 & Ex. 10 at OCP3851. Thus, none of that entity's work involved any "act of the defendant within the state."

Second, Plaintiffs' invocation of Subsection (c)(1) is misguided because their lone cause of action does not arise out of Orchid India's purported contacts with Delaware in any event. As set forth above, Plaintiffs' cause of action exclusively centers on the allegation that "Orchid's submission of ANDA No. 90-044 to the FDA . . . constitutes infringement of the '703 patent under 35 U.S.C. § 271(e)(2)(A)." Complaint at ¶ 47. The ANDA was prepared entirely in India by Orchid India. *See* Ex. 3 (Declaration of Dr. C. Bhaktavatsala Rao, dated February 29, 2008 ("Rao Decl.")) at ¶ 15. The ANDA was filed with the FDA by Orgenus, a New Jersey corporation located in Princeton, New Jersey. *See Id.* at ¶ 14; Ex. 4 (Declaration of Satish Srinivasan, dated March 3, 2008 ("Srinivasan Decl.")) at ¶ 11; Ex. 14 (Declaration of Satish Srinivasan, dated June 18, 2008 ("Srinivasan Suppl. Decl.")) at ¶¶ 12-14. "The 'highly artificial' act of filing an ANDA neither takes advantage of [Delaware's] commercial laws and legal structures nor targets [Delaware's] markets and residents." *Zeneca*, 173 F.3d at 836 (Rader, J., concurring). Put another way, Plaintiffs' cause of action does not involve the breach of a supply agreement involving MCC, packaging materials, or clinical testing—the lone purported Delaware "contacts" identified by Plaintiffs. Therefore, the Court lacks specific jurisdiction over Orchid India under Subsection (c)(1) for this independent reason.

Third, even assuming that Plaintiffs' assertions were true, they at best establish that Orchid India has purchased goods and services from companies located elsewhere but incorporated under Delaware law. However, the United States Supreme Court has suggested that even direct purchases from Delaware would not be a sufficient basis for specific jurisdiction.

See Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 418 n.12 (1984).

(“Arguably, therefore, *Rosenberg* also stands for the proposition that mere purchases are not a sufficient basis for either general or specific jurisdiction.”); *see also Hydrokinetics, Inc. v. Alaska Mech., Inc.*, 700 F.2d 1026 (5th Cir. 1983) (no specific jurisdiction over a nonresident corporation even though it agreed to purchase goods to be manufactured in the forum state, paid for them in the forum state, and traveled there to close the deal). Indeed, given the substantial number of entities incorporated under Delaware law, if transactions with companies incorporated under Delaware law was sufficient to confer jurisdiction under Subsection(c)(1), it is difficult to imagine a transaction that would not give rise to jurisdiction in Delaware.

For the foregoing reasons, none of the “facts” identified by Plaintiffs support specific jurisdiction over Orchid India.

4. Orchid Delaware Is Not The Alter Ego Or Agent Of Orchid India

Plaintiffs’ arguments that Orchid India may be haled into court in Delaware under principles of alter ego and agency for acts of its subsidiary, Orchid Delaware, are both legally irrelevant and factually baseless.

As Plaintiffs acknowledge, “Delaware law allows a court to find jurisdiction over a foreign parent corporation for the acts of its Delaware subsidiary on either alter ego or agency grounds.” Pl. Mem. in Opp. at 21. Here, those theories are irrelevant because Plaintiffs have failed to identify *any* act relative to this case taken by Orchid Delaware that they are attempting to attribute to Orchid India—and there are none. Indeed, Plaintiffs characterize Orchid Delaware as a passive holding company that merely holds stock in a New Jersey company, Orgenus—itsself a defendant in this case—that acted as the U.S. regulatory agent for Orchid India in filing the ANDA at issue in this case. It is undisputed that Orchid Delaware had nothing to do with the filing of that ANDA. Hence, even if Plaintiffs had in fact established a basis for establishing

some form of “alter ego” or “agency” theory, *those theories would do nothing to support jurisdiction over Orchid India in this case*. In short, there is no conduct of Orchid Delaware that has any relevance to this case, making the “attribution to the parent” theories flatly irrelevant to this motion.

In any event, Plaintiffs' reliance on such theories are inapposite as a matter of fact.

a. Orchid Delaware is not the alter ego of Orchid India

Plaintiffs' suggestion that Orchid Delaware allegedly is the alter ego of Orchid India is incorrect but ultimately meaningless. While the theory potentially may allow a court to assert jurisdiction “over a foreign parent for the acts of its Delaware subsidiary,” (Pl. Mem. in Opp. at 21), here, there are simply no “acts” of Orchid Delaware to be attributed to Orchid India with regard to the lone alleged act of infringement—the filing of ANDA No. 90-044. *See id.* at 21-22; *disc. supra* at 6 n.2.

Moreover, in *Mobil Oil Corp. v. Linear Films, Inc.*, 718 F. Supp. 260, 267 (D. Del. 1989), this Court held that for the alter ego theory to operate to pierce the corporate veil, the defendant's corporate form must have been utilized to accomplish fraud or injustice. Similarly, in *Zubik v. Zubik*, the Third Circuit noted that:

limiting one's personal liability is a traditional reason for a corporation. Unless done deliberately, with specific intent to escape liability for a specific tort or class of torts, the cause of justice does not require disregarding the corporate entity. The corporate form itself works no fraud on a [tort victim] who has never elected to deal with the corporation.

384 F.2d 267, 273 (3d Cir. 1967) (footnote omitted) and references cited therein. Plaintiffs do not even allege that the use of the corporate form by either Orchid Delaware or Orchid India was done deliberately and with the specific intent to escape liability with respect to Plaintiffs' alleged claim for infringement. *See Mobil*, 718 F. Supp. at 269.

Orchid Delaware is not the alter ego of Orchid India in any event. It is telling that in none of the cases cited by Plaintiffs did the Court find the alter ego theory applicable. The facts here are far less supportive of the alter ego theory than the facts already considered and rejected by this Court. Initially, “[i]t is entirely appropriate for directors of a parent corporation to serve as directors of a subsidiary, and that fact alone may not serve to expose the parent corporation to liability for its subsidiary’s acts.” *Telcordia Techs., Inc. v. Alcatel S.A.*, C.A. No. 04-874-GMS, 2005 WL 1268061 at * 3 (D. Del. May 27, 2005) (quoting *United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (citations omitted) (noting that it is a “well established principle . . . that directors and officers holding positions with a parent and its subsidiary can and do ‘change hats’ to represent the two corporations separately, despite their common ownership”)).

Second, Plaintiffs’ allege without support that Orchid Delaware and Orchid India commingled funds. However, it is undisputed that the Orchid entities *do not* have joint bank accounts. *See* Ex. 5 (Rao Dep. Tr.) 144:21-145:8.

Third, Plaintiffs further allege that Orchid India funds have paid for all of Orchid Delaware’s obligations, that Orchid Delaware has none of its own revenues or assets, and that Orchid India pays Orchid Delaware’s continuing tax obligations in Delaware. Pl. Mem. in Opp. at 24. Again Plaintiffs’ misconstrue the testimony of Dr. Rao. In fact, Dr. Rao testified that Orchid Delaware received its operating capital through the issuance of stock—hardly an act indicative of an abuse of the corporate form. Ex. 5 (Rao Dep. Tr.) 145:18-147:7.⁶

⁶ Orgenus has also produced documents confirming Dr. Rao’s testimony that: (1) Orchid Delaware issued shares to raise capital (*see, e.g.*, Ex. 11 at ORGN 3, 7, and 8-9); and (2) Orchid Delaware made the corporate decision to incorporate Orgenus (*see, e.g.*, Exhibit 12 at ORGN00001-2).

b. Orchid Delaware is not the agent of Orchid India

Plaintiffs' "agency" theory fares no better. Plaintiffs note that "[u]nder the concept of agency, a court may attribute the actions of one corporation to another" (Pl. Mem. in Opp. at 21), but once again, there are no "actions" of Orchid Delaware to be attributed to Orchid India. *See id.* Indeed, there can be no personal jurisdiction in Delaware over Orchid India based on agency theory because Orchid Delaware had nothing to do with filing the ANDA that gives rise to Plaintiffs' cause of action. *See disc. supra* at 6 n.2. Indeed, Plaintiffs contend that Orchid Delaware is merely a passive holding company. *See* Pl. Mem. in Opp. at 24 ("As discussed above, Orchid [Delaware], in truth, 'doesn't conduct any operations. It doesn't conduct any business activities.'") (quoting Ex. 5 (Rao Dep. Tr.) 25:2-6).

However, even if Plaintiffs had in fact established that Orchid India, Orchid Delaware and Orgenus in fact were three arms of the same business group, there still would be no jurisdiction even under their theory of agency. For example, in *Sears III* the Court held that there was a limited agency relationship between the foreign defendant and its Delaware subsidiary as well as between the foreign defendant and its non-Delaware subsidiaries. *Sears, Roebuck & Co. v. Sears plc*, 752 F. Supp 1223, 1226 (D. Del. 1990) ("Sears III"). Further, the Court held that the limited agency relationships related to the plaintiff's cause of action for trademark infringement. *Id.* at 1266. "The primary issue before the Court [was] whether the claims against [the foreign defendant] for the acts of its non-Delaware subsidiaries are sufficiently related to Delaware so as to justify an exercise of specific jurisdiction over [the foreign defendant] pursuant to § 3104(c)(3)." *Id.* at 1225. The Court in *Sears III* held that there was no personal jurisdiction in Delaware over the foreign defendant for the acts of trademark

infringement it directed its non-Delaware subsidiaries to commit even though the foreign defendant had a Delaware subsidiary. *Id.* at 1226, 1228.⁷

B. The Exercise Of Personal Jurisdiction Over Orchid India Would Violate The Due Process Clause

Even if Plaintiffs had in fact established personal jurisdiction under Delaware law, the exercise of jurisdiction here would violate the Due Process Clause of the United States Constitution. *See Int'l Shoe*, 326 U.S. at 316-17. Due process mandates that the defendant have certain minimum contacts with the forum state to ensure that the lawsuit does not offend “traditional notions of fair play and substantial justice.” *Id.* at 316. When the question before the court is the exercise of personal jurisdiction over an out-of-state accused infringer, the law of the Federal Circuit, “rather than that of the regional circuit in which the case arose,” is applicable. *Akro Corp. v. Luker*, 45 F.3d 1541, 1543 (Fed. Cir. 1995). This analysis inquires into whether: 1) the defendant purposefully directed its activities at residents of the forum; 2) the claims arise out of or relate to those activities; and 3) the assertion of personal jurisdiction is reasonable and fair. *See HollyAnne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1307-08 (Fed. Cir. 1999) (citing *Akro*, 45 F.3d at 1545-46).

The exercise of personal jurisdiction here would offend Federal Due Process. Orchid India cannot be said to have “purposefully directed” any activities towards Delaware, as it does not do any business within the state, has no employees in Delaware, and has no “continuous and systematic” contacts with the state. It cannot be said that Orchid India has “systematic and

⁷ Plaintiffs wrongly argue that “*Monsanto* is readily distinguishable.” Pl. Mem. in Opp. at 26. The question before the Court in *Monsanto* was whether several U.S. companies (which were subsidiaries of a Delaware holding company, which in turn was a subsidiary of the foreign defendants) should be considered “agents” of the foreign defendants and, if so, whether the activities of the U.S. companies within the State of Delaware satisfy the requirements of the Delaware long arm statute. *Monsanto*, 443 F. Supp. 2d at 644-45. The fact that the foreign defendants were holding companies was irrelevant to the *Monsanto* Court’s analysis.

continuous contacts” with Delaware simply because its subsidiary, Orchid Delaware, is incorporated in the state. *See, e.g., Applied Biosystems*, 772 F. Supp. at 1469. Indeed, Orchid Delaware is merely a Delaware holding company, and has nothing to do with ANDA No. 90-044.

Orchid India has no specific or general contacts with Delaware, and certainly no “continuous and systematic general business contacts.” Not one activity relating to Orchid India’s ANDA No. 90-044 occurred in Delaware. Nor did one sale, offer for sale, marketing, or advertising activity for Orchid India’s proposed memantine ANDA product occur in Delaware. Orchid India has no presence in Delaware and does not transact, conduct or solicit any business for any products in Delaware. Moreover, because the accused product has not entered the stream of commerce and is not found in Delaware, or anywhere else in the United States, any contacts with Delaware are insufficient to satisfy the standard required for specific or dual jurisdiction. *Mylan Pharms., Inc. v. Kremers Urban Dev. Co.*, C.A. No. 02-1628-GMS, 2003 WL 1843858 at * 3 (D. Del. Apr. 7, 2003).

Similarly, the exercise of general jurisdiction over Orchid India would be improper because Orchid India is not organized under Delaware law, is not registered as a Delaware entity, has no Delaware offices, facilities, or local telephone listing, has no bank accounts in Delaware, has no employees in Delaware, has no real property in Delaware, and has no agent for service of process or any other purpose in Delaware. Further, Orchid India’s incorporation of Orchid Delaware, two contracts that have a Delaware choice of law provision, and one visit to Delaware on business unrelated to the present cause of action are too minimal to establish continuous and substantial contacts within the purview of the Due Process Clause. The notion that the mere fact of being a parent of a Delaware holding company would render a company subject to personal

jurisdiction in Delaware plainly offends traditional notions of due process. *See, e.g. eSpeed, Inc. v. BrokerTec USA, L.L.C.*, C.A. No. 03-612-KAJ, 2004 WL 2346137 at * 4 (D. Del. Sept. 13, 2004). Even more tenuous are Plaintiffs' alleged indirect contacts with Delaware consisting of several agreements with companies located outside of Delaware, but which allegedly are incorporated in Delaware. The totality of these contacts with Delaware are insufficient to satisfy the high standard required for an assertion of general jurisdiction. *Merck*, 179 F. Supp. 2d at 374. Simply put, Orchid India's business contacts with Delaware and its residents are not continuous and systematic.

Under the agency theory "only the precise conduct known to be instigated by the parent [is attributable] to the parent." *C.R. Bard, Inc. v. Guidant Corp.*, 997 F. Supp. 556, 560 (D. Del. 1998) (quoting *Applied Biosystems*, 772 F. Supp. at 1464). Plaintiffs have offered no evidence of conduct instigated by Orchid India. In the absence of evidence that Orchid India, through its agents, is doing business in Delaware the Court cannot find that the exercise of personal jurisdiction over Orchid India would be fair and just. *Mylan*, 2003 WL 1843858 at * 4. The alter ego theory is applicable only when "the party asserting jurisdiction [has established] some fraud, injustice, or inequity in the use of the corporate form." *Ace & Co., Inc. v. Balfour Beatty PLC*, 148 F. Supp. 2d 418, 425 (D. Del. 2001) (quoting *C.R. Bard*, 997 F. Supp. at 559). Plaintiffs have fallen far short of establishing any of those elements.

Orchid India has far fewer contacts with Delaware than Barr did in the *Merck* case. In that case, this Court analyzed Barr's contacts and concluded "Delaware has no interest in adjudicating this case" which does not involve Delaware related claims or Delaware plaintiffs. *Merck*, 179 F. Supp. 2d at 374-75. So too here, Delaware has no interest in adjudicating this case as it does not involve Delaware plaintiffs and the "highly artificial" act of infringement is

not related to Delaware. Similarly, Orchid India has fewer contacts with Delaware than the defendants in *Mylan* and *Applied Biosystems*. See *Mylan*, 2003 WL 1843858 at * 1 & 3, *Applied Biosystems*, 772 F. Supp. at 1460-62 & 1470.

Contrary to Plaintiffs' assertions, Delaware does not have a strong interest in adjudicating this action. Pl. Mem. in Opp. at 29. This case does not involve Delaware related claims or Delaware plaintiffs, nor were any injuries suffered in Delaware. In addition, Orchid India's has only insignificant contacts with Delaware. Therefore, Delaware has no interest in adjudicating this case. See *Merck*, 179 F. Supp. 2d at 375. Moreover, given Orchid India's insignificant contacts with Delaware it could not reasonably have anticipated being haled into Delaware courts. Geographically, Delaware is a relatively inconvenient forum for both Plaintiffs and Orchid India. The only U.S.-based plaintiff is located in New York, New York, and presumably many of its witness and documents are located there. Orchid India's U.S. regulatory agent for filing ANDAs with the FDA, Orgenus, is located in New Jersey; and it is in New Jersey where relevant documents such as Orchid India's memorial ANDA are located. Thus, New Jersey, rather than Delaware, is a more convenient forum for the parties.

Finally, Plaintiffs' assertions that other defendants have consented to personal jurisdiction in Delaware is flatly irrelevant to the due process analysis. The fact that Plaintiff chose to include in a multiparty case an entity that does not have remotely sufficient contacts with Delaware cannot justify the exercise of jurisdiction over that entity and turns the concept of traditional notions of fairness on its head.

C. The Claims Against Orchid India Should Be Dismissed And Not Transferred

Plaintiffs' final argument requests "that the action against Orchid India be transferred to the District of New Jersey" pursuant to 28 U.S.C. § 1406(a). See Pl. Mem. in Opp. at 31. That statute provides, in relevant part, that a court "in which is filed a case laying venue in the wrong

division or district shall dismiss, or if it be in the interest of justice, transfer such case to any district or division in which it could have been brought.” 28 U.S.C. § 1406(a). Plaintiffs’ cross-motion for transfer thus raises two issues: (1) whether transfer is warranted “in the interest of justice,”; and (2) whether this “case . . . could have been brought” in the United States District Court for the District of New Jersey.

As set forth below, Plaintiffs have not even attempted to address the latter requirement. Because they bear the burden of proof on the issue, but utterly failed to satisfy it, their motion should be denied. Further, the facts of record also reveal that the “interest of justice” does not warrant transfer in any event.

1. Plaintiffs Have Not Met Their Burden of Showing That This “Case . . . Could Have Been Brought” in the District of New Jersey

Plaintiffs baldly assert that transfer is possible because both Orchid India and Orgenus are subject to personal jurisdiction in that district. *See* Pl. Mem. in Opp. at 33. But the plain language of § 1406(a) mandates proof that the entire “case . . . could have been brought” in that district, such that the entire “case” may be transferred. *See* 28 U.S.C. § 1406(a). Plaintiffs’ mistake as to the plain import of § 1406(a) raises two fundamental problems.

First, though Plaintiffs request that the Court “transfer the action against Orchid India to the District of New Jersey” (Pl. Mem. in Opp. at 33), that is a misnomer—there is no such “action.” Rather, this “action” involves nine defendants—Cobalt, Lupin, Orchid India, Orchid Delaware, Teva, Upsher-Smith, Wockhardt USA and Wockhardt Ltd. *See* Complaint at passim. By seeking to transfer a single defendant rather than the entire “case,” Plaintiffs’ cross-motion literally falls outside the ambit of the very statute they seek to invoke and for that reason should be denied.

Second, even had Plaintiffs in fact sought transfer of the entire case, it still would fail. A motion for transfer under § 1406(a) requires proof that the “case . . . could have been brought” in the transferee forum. Accordingly, in evaluating such a motion, a court “must determine whether the court to which transfer is sought is one in which venue would lie and all of the defendants would be subject to the court’s jurisdiction.” *Wild v. Heart of Texas Dodge, Inc.*, No. 01-C-0461-C, 01-C-0463-C, 2001 WL 1913400 at * 2 (W.D. Wisc. Nov. 23, 2001). *See also* 15 Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Federal Practice & Procedure § 3845 (2008) (“It is well settled, of course, that the statute bars transfer to a district or division that would not have been a proper venue in the first instance.”). Here, Plaintiffs do not even purport to make such a showing with regard to Orchid Delaware, Cobalt, Lupin, Teva, Upsher-Smith, Wockhardt USA or Wockhardt Ltd. Thus, Plaintiffs’ contingent cross-motion for transfer should be denied.

2. The Interest of Justice Does Not Warrant Transfer In Any Event

Putting aside the foregoing fatal procedural flaws, Plaintiffs’ contingent motion for transfer should be denied in any event as they have failed to demonstrate that the “interest of justice” warrants transfer of the entire action to the District of New Jersey. Courts examining the “interest of justice” requirement typically require proof that the plaintiff’s decision to file in an improper venue was the product of “good faith” or evidence that the “defendants deliberately misled the plaintiffs about venue.” *Athletes Foot of Delaware, Inc. v. Ralph Libonati Co. Inc.*, 445 F. Supp. 35, 49 (D. Del. 1977) (holding dismissal was the appropriate remedy absent such circumstances). Courts have found the interest of justice lacking, however, where the plaintiff’s attorney could reasonably have foreseen that the forum in which he/she filed was improper. *See Nichols v. G. D. Searle & Co.*, 991 F.2d 1195, 1201-02 (4th Cir. 1993) (affirming district court’s denial of plaintiff’s motion to amend the dismissal order and transfer the case). In the latter

circumstance, courts have determined that the interest of justice is not served by allowing a plaintiff whose attorney has committed an obvious error to impose substantial and unnecessary costs on both the defendant and the judicial system only to seek transfer to a proper court as a backstop. *See Id.* at 1201 (collecting cases).⁸

Here, the circumstances belie Plaintiffs' lone excuse for filing in an improper district—the notion that Orchid India's notice letter allegedly did not “identify Orgenus as [Orchid India's] U.S. regulatory agent for ANDA No. 90-044.” Pl. Mem. in Opp. at 32. First, the regulation Plaintiffs cite, 21 C.F.R. § 314.95(c)(7), provides that “the name and address of an agent in the United States authorized to accept service of process for the applicant” shall be included in the notice letter *if* “the applicant does not reside or have a place of business in the United States.” But Orchid India reasonably believes that it has complied with this regulation by registering to do business in New Jersey and appointing Corporation Service Company of West Trenton, New Jersey as its registered agent. *See* Ex. 13. Moreover, Orchid India's website prominently lists Orgenus as the “Primary Business Contact for US and Canada.” Ex. 14 (Srinivasan Suppl. Decl.) ¶ 2 and Ex. B thereto. Thus, the predicate for Plaintiffs' excuse is simply incorrect.

⁸ The cases Plaintiffs cite to support their motion to transfer are inapposite. In *FS Photo, Inc. v. Picturevision, Inc.*, this Court found personal jurisdiction based on Section 27 of the Exchange Act, which confers personal jurisdiction in all federal courts if a defendant has minimum contacts with the United States. *FS Photo*, 48 F. Supp. 2d 442 (D. Del. 1999). Thus, the question before the *FS Photo* Court was whether to dismiss or transfer based on venue, after determining it had personal jurisdiction. *See id.* at 445, 450. The situation was much the same in *Stein v. Chemtex International, Inc.*, in which the Court also determined it had personal jurisdiction over the defendant, which was incorporated in Delaware. *Stein*, C.A. No. 04-001-SLR, 2004 WL 722252 (D. Del. Mar. 31, 2004). Thus, as in *FS Photo*, the question before the *Stein* Court was whether to dismiss or transfer based on venue, after determining it had personal jurisdiction.

Indeed, apparently armed with that same information, each of the Plaintiffs' counsel have sued Orchid India and Orgenus in the District of New Jersey in other ANDA cases—circumstances which entirely belie the suggestion that Plaintiffs' decision to sue Orchid India in an improper forum was the product of anything other than an intentional, tactical decision by Plaintiffs to bring only one case against multiple defendants despite the obvious jurisdictional hurdles. Thus, in 2006, Plaintiffs' counsel of record in this case at Kirkland & Ellis filed suit against Orchid India and Orgenus—but not Orchid Delaware—in New Jersey for filing two ANDAs with the FDA. *Schering v. Zydus*, 3:06-cv-04715-MCL-TLB. The Complaint alleges, *inter alia*, that Orchid India is registered to do business in New Jersey and has appointed Corporation Service Company of West Trenton, New Jersey as its registered agent, that Orgenus is a New Jersey corporation located in New Jersey, and that “Orchid Ltd., *through its subsidiary . . . Orgenus*, submitted ANDAs 78-356 and 78-357 to the FDA.” See Ex. 15 (Schering Complaint) at ¶¶ 1.E., 1.F., 45. Orchid India and Orgenus did not contest personal jurisdiction. See Ex. 16 (Amended Answer). And Plaintiffs' counsel of record at Jones Day filed another ANDA lawsuit against Orchid India and Orgenus in September 2007 in New Jersey, also without naming Orchid Delaware as a defendant. See *Sepracor Inc. v. Orchid Chemicals & Pharmaceuticals, Ltd.*, C.A. 3:07-CV-04623-TJB-MLC. The Complaint alleges, *inter alia*, that Orchid India is registered to do business in New Jersey and maintains a registered agent in New Jersey for the receipt of service of process, and that Orgenus is a wholly owned subsidiary of Orchid India and is located in New Jersey. Ex. 17 (Sepracor Complaint) at ¶¶ 4, 6. The Complaint further alleges that “Orchid [India], with the participation of Orgenus, [] caused to be filed with the FDA” two ANDAs for its proposed products. *Id.* at ¶ 9. Orchid India and Orgenus

admitted the foregoing allegations of the complaint and did not contest personal jurisdiction.⁹

Ex. 18 (Answer) at ¶¶ 4, 6.

In short, both Plaintiffs' counsel well knew that Orgenus was the entity assisting Orchid India in filing ANDAs (like ANDA No. 90-044) with the FDA. Plaintiffs' decision to ignore that knowledge and instead sue Orchid Delaware was a conscious gambit to seek jurisdiction in an improper forum, not the product of a "good faith" and mistaken belief.

Indeed, Plaintiffs should hardly be excused from the consequences of their conduct and risk-taking. As to the former, Plaintiffs' gambit has indisputably cost Orchid India and Orgenus time and money in briefing the instant motion and participating in extensive jurisdictional discovery (including the production of over 5600 pages of documents and two depositions). As to the latter, not only did Plaintiffs' counsel ignore the information outlined above (publicly disclosed to the very same counsel by Orchid India and Orgenus) but they also deliberately failed to file a so-called "protective suit" in New Jersey, as they did with regard to at least six other ANDA applicants seeking approval to market generic memantine products. The Plaintiffs and their attorneys filed such "protective suits" against GenPharm in the Eastern District of New York, against Mylan in the Western District of Virginia, against Kendle in the Southern District of Ohio, against Sun in the Northern District of Illinois, against Lupin in both the Districts of

⁹ Additional information was available to Plaintiffs and their attorneys that Orgenus assists Orchid India with regard to Orchid's ANDA filings. Thus, pursuant to FDA regulations, Orgenus publicly disclosed the fact that it was Orchid India's U.S. regulatory agent for purposes of a proposed memantine hydrochloride product, *the very same drug at issue in this case*, in a Suitability Petition filed with the FDA on May 18, 2007. See Ex. 14 (Srinivasan Suppl. Decl.) at ¶ 15 and Ex. D thereto.

Maryland and District of Columbia, and against Upsher in the District of Minnesota.¹⁰ *See* Exs.

19-25. In each of these Complaints Plaintiffs included a version of the following allegations:

Plaintiffs have sought to enjoin Defendant's infringing activities as part of an action to enjoin acts of infringement of the '703 patent by numerous defendants filed by Plaintiffs in the District of Delaware. Defendant is properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted if all of Plaintiffs' claims for infringement of the '703 patent are addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendant may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendant succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendant is unsuccessful in any such challenge, Plaintiffs will dismiss this action.

*Id.*¹¹ For reasons known only to Plaintiffs and their counsel, however, they chose not to file such a protective lawsuit against Orchid India in New Jersey. Because the "prejudice" of which the Plaintiffs complain is merely a product of their conduct, they axiomatically cannot satisfy their burden of showing that a transfer is required under section 1406(a) "in the interest of justice."

See, e.g., Athletes Foot at 49.¹²

Accordingly the case against Orchid India should be dismissed.

¹⁰ The corresponding Delaware cases involving those entities have now been consolidated with the instant action.

¹¹ Courts have noted that such protective suits are an acceptable way of addressing the time limit placed on a patentee in filing suit pursuant to the Hatch-Waxman Act. *See, e.g., PDL Biopharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. Civ. 07-11709, 2007 WL 2261386 at * 2 (E.D. Mich. Aug. 6, 2007) (granting a stay in a protective suit due to the "unusual nature" of ANDA claims).

¹² Orchid agrees with Plaintiffs that dismissal of Orchid India for lack of personal jurisdiction would permit "approval of Orchid India's ANDA prior to the expiration of the statutorily-mandated stay." Pl. Mem. in Opp. at 32. Hence the dismissal of the action, rather than transfer, is important because it would allow the FDA to pass on the merits of Orchid India's application, rather than remain stayed from doing so.

IV. CONCLUSION

For all the foregoing reasons, Orchid India's motion to dismiss should be granted, and Plaintiffs contingent motion to transfer should be denied.

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on July 29, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on July 29, 2008, the attached document was Electronically Mailed to the following person(s):

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